

K022584

510(k) CardioTech Antibiotic Hydrogel Wound Dressing  
CardioTech International, Inc.

DEC 3 0 2002

**510(k) Summary**

**CardioTech Antibiotic Hydrogel Wound Dressing**

**Submitters Details:** CardioTech International, Inc.  
78-E, Olympia Avenue,  
Woburn, MA 01801-2057  
Tel: (781) 933-4772  
Fax: (781) 933-3933

**Contact Person:** Michael Szycher, Ph.D.  
Chairman and CEO  
CardioTech International, Inc.  
Tel: (781) 933-4772  
Fax: (781) 933-3933

**Name of Device:** Classification Name: Dressing, Wound  
Common Name: Dressing  
Proprietary Name: CardioTech Antibiotic Hydrogel Wound Dressing  
Device Classification: Unclassified.

**Substantial Equivalence:** CardioTech Antibiotic Hydrogel Wound Dressings are substantially equivalent to MEDIMAC Bandages (Enquay Pharmaceutical Associates, K930457) and Adhesive Bandage with Antibiotic (Johnson & Johnson, K943314).

**Description:** CardioTech Antibiotic Hydrogel Wound Dressings are semi-occlusive, and absorptive. The wound contact surface is composed of an antibiotic containing hydrogel. The OTC antibiotic mixture used consists of the following components: Neomycin Sulfate, 3.5mg, Bacitracin Zinc 500 Units and Polymyxin B Sulfate, 10,000 Units. The antibiotic mixture is present to help prevent bacterial contamination of the dressing. A second outer layer consists of a polymeric film.

**Indications for Use:** CardioTech Antibiotic Hydrogel Wound Dressings are intended for use in the management of partial and full- thickness wounds. They may be used on the following wounds:

Venous stasis ulcers	Superficial burns
Diabetic ulcers	Abrasions and lacerations
Pressure sores	Donor sites
Blisters	



DEC 30 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

CardioTech International, Inc.  
Andrew M. Reed, Ph.D.  
12106 West 75<sup>th</sup> Lane  
Arvada, Colorado 80005-5306

Re: K022584

Trade/Device Name: CardioTech Antibiotic Hydrogel Wound Dressing  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: October 31, 2002  
Received: November 7, 2002

Dear Dr. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

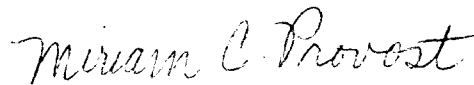
Page 2 – Dr. Andrew M. Reed

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., MD  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) CardioTech Antibiotic Hydrogel Wound Dressing  
CardioTech International, Inc.

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**PREMARKET NOTIFICATION**  
**INDICATIONS FOR USE STATEMENT**

510(k) Number: K022584  
CardioTech International, Inc.

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Blisters

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Donor sites

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

*Miriam C. Provost*  
Division Sign-Off  
Division of General, Restorative  
and Neurological Devices

(Optional Format 1-2-96)

K022584